

25. The method of claim 21, wherein the method is reducing lipid synthesis in subcutaneous adipose tissue.

A3 26. The method of claim 21, wherein the method is reducing triglyceride synthesis in subcutaneous adipose tissue.

REMARKS

Claims 1 to 3, 5 to 11, and 14 to 20 remain pending in the application. Claims 4, 12 and 13 have been canceled. Claims 21 to 26 have been added.

This Preliminary Amendment is characterized as such since it is the first communication submitted by the Applicants since the RCE was filed on August 2, 2001 and since it is submitted prior to any known non-withdrawn office action issued by the PTO since the RCE was filed. A first request for Suspension of Action was submitted concurrently with the RCE. The first Request for Suspension of Action (First Request) was granted by the PTO in a Communication dated August 7, 2001. A Second Request for Suspension of Action, dated November 9, 2001 (Second Request), was submitted by the Applicants. Prior to acting on the Second Request, the PTO issued an Office Action dated December 11, 2001, constituting a Final Rejection (Office Action). Upon receipt of the Office Action, Attorney Dean contacted Ms. Liliano DiNola-Baron, the Examiner in charge of the present application, by telephone to inquire about the status of the Second Request. The Examiner indicated that the Second Request had not been acted upon and requested that a copy of the Second Request be transmitted to her via facsimile. The Examiner later contacted

Attorney Dean by telephone and informed him that the Second Request had been granted and the Office Action withdrawn. In view of that withdrawal, the Applicant wishes to submit the present Preliminary Amendment.

In the Office Action dated March 2, 2001, claims 1 to 13 and 18 to 20 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,032,408 to Schrueder. In particular, the Action urges that the Schrueder patent discloses treatment of skin conditions, such as cellulitis and striae. Treatment compositions of this patent were said to provide paraffinic oils and esters of unsaturated natural fatty acids and fatty alcohols derived from various natural sources, including perilla oil.

Claims 1 to 13 and 18 to 20 patentably distinguish over the Schrueder patent. Independent method claims 1 and 18 require the topical application of a PPAR stabilizer. The Schreuder patent does not disclose the topical application of PPAR stabilizers, including perilla oil.

The Schreuder patent does not disclose the topical application of perilla oil or perilla seed oil. The Schreuder patent discloses topical application of esters of higher natural fatty acids and alcohols such as oleyl oleate or oleyl decalate (col. 1, lines 37 to 41), but does not disclose the triglyceride type esters normally found in natural oils such as perilla oil and perilla seed oil. The Schreuder patent further discloses perilla seed oil as an example of a natural product from which higher natural fatty acids or alcohols may be derived (col. 1, lines 42 to 47). Although perilla seed oil is fatty in nature and, thus, contains triglycerides, those triglyceride types of esters are different in structure than the esters disclosed in

the Schreuder patent. The representative esters in Schreuder, oleyl oleate or oleyl decalate, do not have a triglyceride structure. They are typically manufactured from triglycerides in the manner disclosed in part in Organic Chemistry by McMurry, 4th edition, Brooks/Cole Publishing Company, © 1995, page 1100, a copy of which is incorporated herein by reference. In the reaction at page 1100, a triglyceride(s) is converted to a glycerol(s) and a fatty acid(s). The fatty acid(s) must then be subsequently converted to those types of esters disclosed in the Schreuder patent (oleyl oleate or oleyl decalate). Therefore, the esters disclosed in the Schreuder patent do not correspond in structure to those triglyceride type esters naturally present in perilla oil and perilla seed oil and cannot be construed as corresponding to those oils. Thus, the teachings of the Schreuder patent cannot anticipate the claims 1 to 13 and 18 to 20.

Dependent claims 6 to 9 further distinguish over the teachings of the Schreuder patent. The claims relate to topical application of a PPAR stabilizer to treat or ameliorate an affected area of the skin the conditions of oily skin (claim 6), oily hair or oily scalp (claim 7), blemishes (claim 8) and skin break out (claim 9). The Schreuder patent discloses skin disorders such as cellulitis or striae (column 1, lines 8 to 14). The Schreuder patent does not specify treatment or amelioration of any of the conditions set forth in claim 5 to 9. Thus, claims 5 to 9 clearly are patentable over the disclosure of the Schreuder patent.

In the Office Action, claims 1 to 13 and 18 to 20 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,882,664 to Soma et al. The Soma et al. patent was said to disclose a composition for topical application that has

an extract from a plant of the family Labiatae, such as the genus Perilla, for enhancing hyaluronic acid productivity. Decrease in such productivity was said to be linked to dermal aging. The composition was further described as containing 0.0001 to 20% by weight of the extract.

Claims 1 to 13 and 18 to 20 patentably distinguish over the teachings of the Soma et al. Patent. Independent claims 1 and 18 require that a PPAR stabilizer be applied to an affected area exhibiting conditions selected from the group consisting of blemishes, skin breakouts, cellulite, oily skin, oily hair, oily scalp, and any combination thereof. The Soma et al. patent discloses certain symptoms of dermal aging, such as wrinkles, but does not disclose any of the foregoing skin conditions or any relationship between enhancing hyaluronic acid productivity and those conditions. Thus, the Soma et al. patent cannot be said to anticipate any of claims 1 to 13 and 18 to 20.

Claim 20 further distinguishes over the Soma et al. patent. Claim 20 requires treatment of delineated conditions resulting from or accompanied by PPAR upregulation. The Soma et al. patent fails to disclose PPAR upregulation or suggest that enhancing hyaluronic acid productivity has any effect on PPAR upregulation. Moreover, the patent does not disclose any of the delineated conditions of cellulite, oily skin, oily hair, oily scalp, blemishes and skin break out, let alone disclose any relationship between enhancing hyaluronic acid productivity and those conditions. Thus, the Soma et al. patent cannot be said to anticipate claim 20.

In the Office Action, Claims 1 through 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Soma et al. patent in view of U.S. Patent No. 4,560,555 to Snider. The

Snider patent was described as disclosing reactive polymers for the treatment disorders. Component A of the polymer was described as obtainable from a natural oil.

Claims 1 through 20 distinguish over the combination of the teachings of the Soma et al. patent and the Snider patent for the reasons stated above in the 102(e) rejection above and further because the Snider patent does not disclose or suggest the topical application of perilla oil or fish oil. By the time the disclosed composition is topically applied, the natural oil, which may be perilla oil, fish oil or one of numerous others, has been altered chemically to a material degree. Thus, combination of the teachings of the two cited patents does not yield the claimed present invention.

It is submitted that the chemically processed natural oil of the Snider patent is not a natural oil at all. The Snider patent discloses reactive polymers for the treatment of skin afflictions. These reactive polymers, component A and component B, must be mixed at the time of use (i.e., just before application to the skin) because, upon such mixing and after application to the skin, the reactive polymers cross-link with skin proteins. Component A may be derived from a natural oil, such as fish oil or perilla oil (col. 4, lines 4 - 11). However, the natural oil must be "pre-reacted with polyvalent alcohols with consequent formation of hydroxylated glycerid (sic) successively reacted with carboxylic acids" (emphasis added) (col. 4, lines 4-7) to produce component A. Component A is actually a prepolymer, which must be an oligomer having hydroxylic, amidic or aminic chemical functions (col. 2, lines 54-55) in order to react with component B when mixed. This required modification of natural oils to provide the prepolymer component A is illustrated in the examples (see col. 4, line 55 through col. 6, line 61,

specifically examples 4, 6, 7 and 10 where soya-bean oil, fish oil and castor oil are reacted to form prepolymers).

Given that component A of the Snider patent is not a natural oil and that none of the disclosed natural oils are actually topically applied, it would not be obvious to modify the composition and method of treatment disclosed in the Soma et al. patent with the perilla oil and dish oil purportedly disclosed in the Snider patent.

Independent claim 14 and dependent claim 15 further distinguish over the combination of the teachings of the Soma et al. and Snider patents. Claims 14 and 15 are directed to the treatment of acne. Acne is not mentioned in either the Soma et al. patent or the Snider patent. Further, claims 14 to 15 require certain proportions of alpha-linolenic acid and eicosapentaenoic acid. Neither of the patents nor their combination disclose such acids or such proportions.

New claims 21 to 26 are directed to the topical application of a PPAR stabilizer to improve the appearance of the skin by (1) reducing oil production by sebaceous glands, (2) reducing lipid synthesis in subcutaneous adipose tissue, and/or (3) reducing triglyceride synthesis in subcutaneous adipose tissue. None of these end uses are disclosed in any of the cited patents.

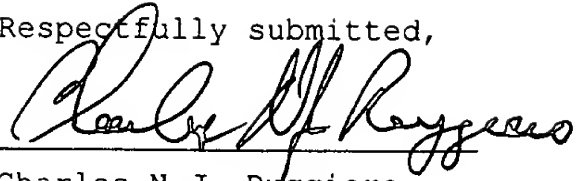
The claims also appear in the attachment referred to as

VERSION WITH MARKINGS TO SHOW CHANGES MADE.

Reconsideration of claims 1 to 20 is deemed warranted in view of the foregoing, and allowance of those claims and new claims 21 to 26 is respectfully requested.

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Charles N.J. Ruggiero", written over a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Once amended) A method of treating or ameliorating a condition selected from the group consisting of one or more blemishes, skin breakouts, cellulite, oily skin, oily hair, oily scalp and any combination thereof [an affected area of the skin or hair] comprising topically applying to [the] an affected area of the skin or hair a PPAR stabilizer in an amount effective to improve the aesthetic appearance of the affected area.

Claim 4 is cancelled.

5. (Once amended) The method of claim [4] 1, wherein the condition is cellulite.

6. (Once amended) The method of claim [4] 1, wherein the condition is oily skin.

7. (Once amended) The method of claim [4] 1, wherein the condition is oily hair or oily scalp.

8. (Once amended) The method of claim [4] 1, wherein the condition is one or more blemishes.

9. (Once amended) The method of claim [4] 1, wherein the condition is skin break out.

10. (Once amended) The method of claim [4] 1, wherein the PPAR stabilizer is applied in the form of a topical composition having [comprises] from about 0.01 wt% to about 10 wt% of the PPAR stabilizer.

Claims 12 and 13 have been cancelled.